Medical Coverage Policy | Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

EFFECTIVE DATE: 03|01|2018
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OVERVIEW

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompressive surgery or as an alternative to decompressive surgery.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products
Not applicable

POLICY STATEMENT

BlueCHiP for Medicare
Interspinous or interlaminar distraction devices as a stand-alone procedure are not covered as a treatment of spinal stenosis as the evidence is insufficient to determine the effects of the technology on health outcomes.

Use of an interlaminar stabilization device following decompression surgery is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Removal for medical reasons (device failure, infection, etc.) is covered for all members. However, insertion of a replacement device after removal is not covered.

Commercial Products
Interspinous or interlaminar distraction devices as a stand-alone procedure are not medically necessary as a treatment of spinal stenosis as the evidence is insufficient to determine the effects of the technology on health outcomes.

Use of an interlaminar stabilization device following decompression surgery is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Removal for medical reasons (device failure, infection, etc.) is covered for all members. However, insertion of a replacement device after removal is not medically necessary.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Spinal Stenosis

Lumbar spinal stenosis (LSS), which affects over 200,000 people in the United States, involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of LSS is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Some sources describe the course of LSS as "progressive" or "degenerative," implying that neurologic decline is the usual course. Longer term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.

The lack of a valid classification for LSS contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient. This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.

Treatment

The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher spondylolisthesis or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

Surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for LSS should be considered only after a patient fails to respond to conservative treatment, but there is no agreement about what constitutes an adequate course or duration of treatment.

The term "conservative management" may refer to "usual care" or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical vs nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each site decide what to offer. A subgroup analysis of the SPORT trial found that only 37% of nonsurgically treated patients received physical therapy in the first 6 weeks of the trial and that those who received physical therapy before 6 weeks had better functional outcomes and were less likely to cross over to surgery later. These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise. Patients with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery vs an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of patients who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.

Diagnostic criteria for fusion surgery are challenging because patients without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain. The SPORT trial did not provide guidance on which surgery is appropriate for patients who do not have spondylolisthesis, because nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis patients at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to the better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis. However, in 2016, findings from two randomized trials of decompression alone vs decompression plus fusion were published. The Swedish Spinal Stenosis Study (SSSS) found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with or without degenerative spondylolisthesis. The Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in patients who had spinal stenosis with grade 1 spondylolisthesis (3-14 mm). The patients in SLIP who had laminectomy alone had higher reoperation rates than those in SSSS, and the patients who underwent fusion had better outcomes in SLIP than in SSSS. While some interpret the studies to reflect differences in patient factors-in particular, SSSS but not SLIP included patients with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns. As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the patients before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings. A small trial conducted in Japan, Inose et al (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the patients also had dynamic instability. Certainty in the findings of this trial is limited because of its size and methodologic flaws.

Spacer Devices

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; they are not discussed in this evidence review.

Interspinous Implants
Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers
Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

The Superion® Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment.

The coflex® Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex® (previously called the Interspinous U) is indicated for use in 1- or 2- level lumbar stenosis from the L1 to L5 vertebrae in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of nonoperative treatment. The coflex® "is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s)."

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), although a number of them are in trials at U.S. centers. As of April 2018, only the X-STOP, coflex, and Superion Interspinous Spacer (ISS) devices had received FDA approval for use in the United States. Manufacturing of the X-STOP device stopped in 2015.

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes 2 randomized controlled trials of 2 spacers (Superion Interspinous Spacer, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown a high failure and complication rates. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion Interspinous Spacer on some measures. For example, the trial reported more than 80% of patients experienced improvements in certain quality of life

outcome domains. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraX ion trial. Functional outcomes and pain levels were similar in the 2 groups at 1-year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, the evidence includes two RCTs with a mixed population of patients. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in two situations-as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). For decompression with coflex vs decompression with lumbar spinal fusion, the pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success (CCS) measure. A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs 157 minutes; $p<0.001$) and blood loss (106 vs 336 ml, $p <0.001$). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index (ODI), visual analog scale and Zurich Claudication Questionnaire scores after two years.In that analysis, 62.8% of coflex patients and 62.5% of fusion patients met the criteria for operative success. The efficacy of the comparator in this trial is uncertain because successful fusion was obtained in only 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The report indicated no significant differences in ODI or visual analog scale between the patients with pseudoarthrosis or solid fusion but Zurich Claudication Questionnairescores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group and 14% in the coflex group ($p=0.18$), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in patients with grade 1 spondylolisthesis is needed. In an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the ODI, between the patients treated with coflex plus decompression vs. decompression alone. CCS-defined as a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit, was used to assess superiority. A greater proportion of patients who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the CCS was primarily driven by a greater proportion of patients in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their knowledge of the patient's treatment. Consequently, including this component in the CCS measure might have overestimated the potential benefit of treatment. Analysis was not reported separately for the group of patients who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population. Limitations of the published evidence preclude determining the effects of the technology on net health outcome, and evidence reported through clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device. Consideration of existing studies as indirect evidence regarding the outcomes of using

spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the CCS measure. However, in addition to concerns about the efficacy of fusion in this study, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and back pain; thus demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study and the Spinal Laminectomy versus Instrumented Pedicle Screw, 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. Therefore, demonstrating the noninferiority of coflex plus spinal decompression vs spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgoup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal IDE trial have been published, but comparison with decompression alone in this population has not been reported.Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input is not generally supportive of a clinically meaningful improvement in net health outcome, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

22867 Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

22868 Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (list separately in addition to code for primary procedure)

22869 Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level

22870 Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (list separately in addition to code for primary procedure)

C1821 Interspinous process distraction device (implantable)

There is no specific CPT code for the removal of interlaminar/interspinous process stabilization/distraction devices, therefore, an appropriate Unlisted CPT code should be used.

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, June 2020
Provider Update, April 2019
Provider Update, February 2019
Provider Update, January 2018
Provider Update, January 2017

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